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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/673,872

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Tony Wai-Chiu So

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03/03/2010

Glaxo Smith Kline

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EXAMINER

WELTER, RACHAEL E

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

03/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/673,872	Applicant(s) WAI-CHIU SO ET AL.	
	Examiner RACHAEL E. WELTER	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,8,12-16,19,21,23,24,26,29 and 139-161 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, 6, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/2/09, 2/3/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/2/09 has been entered.

Claim Status

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161 are pending. Claims 2, 5-7, 9-11, 17-18, 20, 22, 25, 27-28, and 30-138 are cancelled. Claims 139-161 are newly added.

Information Disclosure Statements

The information disclosure statements (IDS) submitted on December 2, 2009 and February 3, 2010 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. A signed copy of forms 1449 are enclosed herewith.

Claim Objections

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The objection to claims 1, 21 and 112 is withdrawn in light of applicant's amendments.

Withdrawn Rejections

The rejection of claims 1, 21, and 112 and its dependent claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's persuasive arguments.

The rejection of claims 1-4, 6, 8, 12, 13, 15-16, 19-21, 23-24, 26, 29, 112, 114, 118-125, 128, 131-132, 135-138 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of WO 97/12602 to Weiner et al or Yu et al (EP0273202) is withdrawn in light of applicant's arguments.

The rejection of claims 14, 30-33, 36-40, 43-44, 133 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of WO 97/12602 or Yu et al (EP0273202) respectively in further view of Uchikawa et al (5,156,836) is withdrawn in light of applicant's arguments.

The rejection of claims 1-4, 6, 8, 12-13, 15-16, 19-21, 23-24, 26, 112, 118-125, 128, 131-132, 135-138 rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07-048230 in view of WO 97/12602 or Yu et al (EP0273202) respectively in further view of Caldini et al (4,272,516) is withdrawn in light of applicant's amendments.

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The rejection of claims 1-4, 6, 8, 12-13, 15-16, 19-21, 23-24, 26-29 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03638 to Navarro et al in view of WO 97/12602 to Weiner et al is withdrawn in light of applicant's amendments.

The rejection of claims 14, 30-33, 36-40, 43-44, 112, 118-125, 128, 131-138 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03638 to Navarro et al in view of WO 97/12602 to Weiner et al in further view of Wong et al (5,130,142) is withdrawn in light of applicant's amendments.

The rejection of claims 30-31, 36-40, 43-44, 112, 114, 118-125, 128, 131-132, 135-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03638 to Navarro et al in view of WO 97/12602 to Weiner et al in further view of WO 88/01863 to Peck et al is withdrawn in light of applicant's amendments.

The rejection of claims 1-4, 6, 8, 12-13, 15-16, 19-21, 23-24, 26, 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5183817) in view of WO 97/12602 or Yu et al (EP0273202) is withdrawn in light of applicant's amendments.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, 139, 141-144, 146-151, and 153-160 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of Yu et al (EP0273202).

Peck teaches a quick breaking foam to treat baldness comprising (a) 1-5% minoxidil; (b) 10-50% propylene glycol; (c) 30-75% alcohol; (d) 0.5-10% emulsifier and/or surfactant; (e) 0.1-5% hydroxypropyl methylcellulose; and (f) 10-50% water wherein the composition is actuated with a propellant. See page 2. Peck teaches the minoxidil may be selected from any known analog. Peck teaches skin penetrates including alcohol such as dodecanol and oleyl alcohol. See page 5. Peck teaches various surfactants in the composition including Tween 80 (polysorbate) and Span 60 to improve the stability of the composition. See page 6, lines 20-25. Included in the class of emulsifiers is lauryl alcohol, isostearyl alcohol, and cocamide DEA. See page 6, lines 10-17. Peck teaches the use of minoxidil or a salt thereof. See page 5, lines 25-30. Propellants taught by Peck include hydrocarbons, such as propane, isobutene, or dimethyl ether and chlorofluorocarbons. See page 6, lines 2-6.

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Peck does not teach the instant acid salt.

Yu et al teach additives such as hydroxy acids enhance the therapeutic effects of pharmaceutical and cosmetic actives in topical treatments. See page 2. The pharmaceutical or cosmetic active is utilized generally in the amount of 0.01-40% and the hydroxyl acid is used in the amount of 0.01-99%. See page 6. Yu teaches the use of 3% lactic acid with minoxidil to help the minoxidil dissolve in the solution and enhance penetration and the efficacy of minoxidil on hair growth. The pH of the solution is 4.7. See example 3.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teaching of Peck and Yu et al and utilize the instant acid. One would be motivated to do so since Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, a skilled artisan would have been motivated to add an acid to form a minoxidil acid salt for enhanced penetration of minoxidil into the hair follicle.

Regarding the recitations of “at least 5%” of minoxidil salt and 7.5 to 12% by weight, Peck teaches minoxidil in an amount of 1-5%. “At least 5%” includes 5.00001%, 5.001%, etc, which is considered obvious over the prior art’s “5%”. Furthermore, it would have been obvious to a skilled artisan at the time the invention was made to manipulate the concentration of minoxidil during routine optimization in order to achieve a concentration of 7.5 to 12% by weight. One would have been motivated to do so depending on the desired “strength” of the composition and to meet the needs of a

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particular patient population. Drug concentration is a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Regarding the instantly claimed ratio of ethanol to water, Peck sets forth a general range of components wherein the alcohol is utilized in an amount of 30-75% and water from 10-50%, thus it is within the skill of an artisan to look at the guidance provided by Peck and manipulate the concentrations (ratio) of water and ethanol depending on the concentration of the other components. It should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding the instant pH of the final product, Yu suggests a minoxidil composition with a pH of 4.7, which reasonably reads on a pH of "approximately 5.0-7.0." Furthermore, it would have been obvious to incorporate a pH within the range of 5.0-7.0 in the composition of Peck because its compositions are administered to the skin/scalp and such a neutral pH range would not be harmful and/or irritating.

Response to Arguments

Applicant's arguments and supplemental arguments filed 12/2/09 and 2/3/10 respectively have been fully considered but they are moot in view of the new rejection

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presented above and unpersuasive in regard to Peck and Yu, which were references used in previous rejections. Accordingly, the examiner will address any arguments presented by applicant which are still relevant to either Yu or Peck.

Applicant argues that the examiner has not established a prima facie case of obviousness. Applicant argues that the PTO must satisfy three requirements. The PTO must provide a reason to combine the elements in the prior art, a reasonable expectation of success, and the reference or combination of references should teach all the claimed limitations. Applicant argues that a prima facie case of obviousness has not been established because Peck et al and Yu et al fail to teach or suggest all the limitations of the claims.

As acknowledged by applicant, the critical question in establishing a prima facie obviousness case is to “identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does...” KSR International Co. V. Teleflex Inc., 550 U.S. -, 82 USPQ2d 1385 (2007). In the instant case and as set forth in the rejection, Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, clearly the examiner has identified the motivation that would have prompted a skilled artisan to combine an acid to Peck’s composition. A skilled artisan would have been motivated to add an acid to form a minoxidil acid salt for enhanced penetration of minoxidil into the hair follicle.

The second question is whether there is a reasonable expectation of success. In instant case and as set forth in the rejection, Peck teaches the use of minoxidil or a salt

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thereof. See page 5, lines 25-30. It is known in the pharmaceutical art that the addition of the acid forms a salt and thereby makes the active compound, i.e. minoxidil, more soluble. Hence, the penetration of the compound into the skin is increased. Therefore, a skilled artisan would have *reasonably* expected success in adding acid to Peck's composition.

It is incumbent upon the applicant to answer the question "whether the improvement is more than the predictable use of prior art elements according to their established functions", which applicant has not done. It is noted that applicant argues that the addition of a salt increases minoxidil's solubility; thus requiring less co-solvent. However, as discussed above, this is a well known concept in the pharmaceutical art (the addition of the acid forms a salt and thereby makes the active compound hydrophilic and more soluble). Hence, solubilizing the active allows increased penetration of the compound into the skin. This is established by Yu. Yu teaches adding the acid makes it more soluble and increases penetration of minoxidil. In summary, applicant has not shown any unexpected results in rebutting that it is prima facie obvious to combine prior art element to yield a ***predictable result***. Further, it should be noted that, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)." Applicant has not provided any factual evidence establishing unobviousness.

Furthermore, the combination of references teaches all the claimed limitations, specifically a composition having both at least 5% minoxidil or a pharmaceutically

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acceptable salt thereof and less than 10 wt.% polyhydric alcohol. As set forth in the rejection, it is the examiner's position that the recitation of "at least 5%" is rendered obvious by Peck. "At least 5%" includes values such as 5.00001%, 5.001%, etc, which is obvious over the prior art's "5%" since it is conventional to optimize the prior art's range during routine experimentation. Similarly, it is the examiner's position that less than 10% is rendered obvious by Peck. "Less than 10%" includes values 9.9999%, 9.99%, etc., which is obvious over the prior art's 10%.

Applicant argues that Peck teaches away from the instant invention because formulations described in the examples of Peck require high percentages of propylene glycol to achieve high minoxidil concentrations. According to applicant, Peck teaches formulations (examples 5 and 6) with both high concentrations of minoxidil, i.e., 5% and high concentrations of propylene glycol, i.e., 50%. Furthermore, applicant argues that Peck does not describe or exemplify an advantage of having both reduced levels of polyhydric alcohol (less than 10%) and a high loading of minoxidil (at least 5%). As such, applicant argues that Peck does not establish utility of the presently claimed composition and does not qualify as an enabling prior art reference.

Although the examples are noted, the examiner points out that the instant rejection is made under obviousness and not anticipation. Therefore, the criteria for establishing a case of prima facie obviousness is not whether the prior art exemplifies all the claimed limitations but whether the prior art suggests the claimed limitations. As acknowledged by applicant, Peck teaches a general range of both minoxidil and

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polyhydric alcohol. This is sufficient in establishing obviousness. Additionally, the examiner directs applicant's attention to MPEP 2123, II: "Disclosed examples and preferred embodiments **do not constitute a teaching away form the broader disclosure** or nonpreferred embodiment". In response to applicant's argument that Peck fails to meet the necessary statutory requirements of adequate enablement, the examiner directs applicant's attention to MPEP 2121. According to MPEP, "When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability." *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Although applicant has questioned the enablement of Peck, applicant is merely arguing and has not provided any evidence or facts to show that the reference is improper or inadequate.

The remarks of applicant are further supported by the declaration submitted by Barry Hunt. Hunt declares that the compositions in Peck contain a very high percentage of polyhydric alcohol propylene glycol in order to improve the solubility of minoxidil. According to Hunt, such high amounts of polyhydric alcohol are not pharmaceutically or cosmetically elegant and may be unacceptable to the consumer causing local irritation and hypersensitivity upon application to the scalp.

However, the Rule 132 Declaration under 37 CFR 1.132 by Barry Hunt is insufficient to overcome the rejection of the claims as set forth in the last Office action because:

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It is noted that the Declaration provided by Barry Hunt is an opinion Declaration. "Although an affidavit or declaration which states only conclusions may have some probative value, such an affidavit or declaration may have little weight when considered in light of all the evidence of record in the application." In the instant case, the Declaration provided Barry Hunt only provides conclusions without any probative value, i.e. evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, etc. It appears the statements are only remarks to the Office Action in a Declaration form. Further, it is noted that Mr. Hunt makes statements such as "may be unacceptable to the consumer, and may cause local irritation" without providing evidence to substantiate such statements. Therefore, the Rule 132 Declaration is unpersuasive.

Applicant further argues that Yu does not cure the deficiencies of Peck and only teaches a 2% minoxidil formulation and a large polyhydric content. According to applicant, Yu does not teach or suggest a composition having both at least 5% minoxidil and less than approximately 10% by weight polyhydric alcohol.

In response to applicant's arguments regarding Yu, it is the examiner's position that Peck renders instant recitation "at least 5% minoxidil" and "less than 10%" obvious. As such, Yu is not relied upon to cure this deficiency. Yu is merely relied upon to provide motivation to utilize an acid to form a salt.

Applicant further presents sales data from Nielsen, which shows data from 2005 through 2009 for minoxidil topical solution which contains 5% minoxidil, water, alcohol,

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and propylene glycol (MTS) and the presently claimed minoxidil topical foam which contains 5% minoxidil in a hydroalcoholic, propylene glycol-free, unencapsulated formula (MTF). Applicant notes that the numbers in the Nielsen data clearly indicate a steady increase in sales of the present MTF and a steady decrease in the sales of MTS.

In response to applicant's evidence of commercial success, the examiner argues that such results are not convincing because applicant has not compared the alleged successful results to the closest prior art, in this case, Peck. According to MPEP 716.02, an affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. *In re Burckel*, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). Thus, in order to be persuasive, applicant must demonstrate that the presently claimed invention has had a bigger success commercially than the invention of Peck. Furthermore, according to MPEP 716.03, "Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. *In re Tiffin*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971). As such, since Peck teaches 10% propylene glycol and the instant claims suggest up to 10% propylene glycol, applicant should be comparing minoxidil compositions within this range of co-solvent in order to be commensurate in scope with the instant claims. However, it is unclear from applicant's description how much propylene glycol is present in MTS and whether or not higher concentrations of propylene glycol in MTF would have as much success. Moreover, the examiner notes that according to MPEP 716.04, "Gross sales figures do not show commercial success

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absent evidence as to market share,” *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed.Cir. 1985), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, *Ex parte Standish*, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988). As such, since applicant has shown no evidence of market share and what sales would normally be expected in the market, applicant's commercial success is insufficient.

Lastly, applicant argues unexpected results and notes that the claimed compositions (MTF) exhibited unexpected improved properties as compared to MTS as evidenced by Olsen. Applicant notes that the MTF treated group showed a 34% improvement over the MTS treated group. Applicant further contends that the presently claimed minoxidil composition showed increased uptake of minoxidil over 5% MTS at 1 and 2 hours of application. Applicant argues that one study compared 5% MTS to the present 5% MTF and showed the systemic absorption of the 5% MTF with twice-daily application of 1 g in men was about half of that observed with 5% MTS with twice-daily application of 1cc. Applicant further submits that consumer use studies showed that the minoxidil foam vehicle was rated significantly higher on several aesthetic attributes compared with minoxidil solution, including ease of application, lack of dripping, quick absorption and drying, and ability to fit easily into a daily routine. As such, applicant contends that any prima facie case of obviousness is rebutted by the above-discussed evidence of the unexpectedly superior properties of the claimed minoxidil composition.

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In response to applicant's unexpected results, the examiner argues that such results are not convincing because applicant appears to be making an improper comparison given what is known in the prior art. Applicant appears to be comparing the success of a minoxidil foam to a minoxidil solution. However, this is improper because the prior art (Peck) teaches a foam and as such, one would expect rather than unexpected the improved properties as evidenced by Olsen. Furthermore, the examiner contends that the instant claims are not commensurate in scope with the unexpected results. According to MPEP 716.02, whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In this case, the MTF does not contain any propylene glycol. However, the examiner notes that instant claims 1 and 21 recite that propylene glycol can be in an amount of up to 10%. Moreover, it is not clear if an acid is present in the MTF to solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt.

As such, absent any unexpected results and results commensurate in scope with the instant claims, it is the position of the examiner that the teachings of Peck in view of Yu would lead one of ordinary skill in the art to arrive at the instantly claimed invention.

Claims 140, 145, 152, and 161 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of Yu et al (EP0273202) as

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applied to claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, 139, 141-144, 146-151, and 153-160 and in further view of Uchikawa et al (5,156,836).

The teachings of Peck and Yu have been set forth above.

Peck does not teach the elected glycerol co-solvent or the use of an antioxidant.

Uchikawa teaches a hair revitalizing composition that may comprise minoxidil.

Uchikawa teaches conventional excipients used to formulate hair-revitalizing compositions include polyhydric alcohols such as glycerine and propylene glycol, antioxidants, etc. see column 4, lines 5-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute the exemplified propylene glycol with the instantly claimed glycerol and arrive at the instant invention. One would have been motivated to do so since Uchikawa teaches both propylene glycol and glycerol are polyhydric alcohols conventionally used in the art. Therefore, a skilled artisan would have expected similar results absent unexpected results by using any conventional polyhydric alcohol known in the art in the composition. Further, it would have been obvious for a skilled artisan to further utilize a conventional excipient such as an antioxidant as taught by Uchikawa to prevent oxidation.

Response to Arguments

Applicant's arguments filed 12/2/09 and 2/3/10 have been fully considered but they are not persuasive.

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Applicant argues the merits of Peck and Yu.

These arguments have been addressed above and are incorporated herein. The examiner notes that Uchikawa is only relied upon to teach the instant co-solvent and applicant has not argued this.

As such, it is the examiner's position that the instant claims are rendered obvious over Peck, Yu, and in further view of Uchikawa.

Conclusion

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/

Primary Examiner, Art Unit 1611

February 27, 2010